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# Medical imaging clinical trials unit: A professional need

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ABSTRACT

*Purpose:* To design and describe a management and control tool and the human resources needed to efficiently manage the imaging process within clinical trials for a better quality of care for the patient.
*Methods:* A unit was created to efficiently organise the participation of our Medical Imaging Department in clinical trials. This entity was defined and monitored using a customized, flexible and modular software package that provides the necessary information to execute and monitor requests (appointments, protocols, reports, complaints, billing). Various indicators of activity and professional satisfaction were parameterised.
*Results:* From 2016 to 2020, 367 trials were participated and monitored, 50% of all the hospital clinical trials. The budget of the Medical Imaging Department grew by 47% in this period. The coordination with other departments and principal investigators improved, as shown by surveys (62% fluid and 38% very fluid), with a high perception of collaboration (86%).
*Conclusions:* The implementation of a Medical Imaging Clinical Trials Unit involve identifying the tasks, personnel, organisational needs, workflow, monitoring and invoicing. The creation of this Unit has improved the control and traceability of clinical trials within the Department.

## 1. Introduction

Most clinical trials are randomised experimental studies aiming to evaluate the efficacy and safety of a treatment in a select group of patients [1]. Clinical imaging plays a fundamental role in many clinical trials. Different imaging modalities are often used for the initial detection and staging of lesions, to assess response to treatment, and to define adverse effects. In addition, imaging biomarkers are becoming useful to evaluate the biological effects of treatments [2].

Both Radiology and Nuclear Medicine departments are actively involved to carry out the scheduled imaging studies, although the addition of these exams increases the burden of daily workflow [3]. Different organisational strategies have been adopted to establish clinical trials units that act independently on an operational and financial level. In our university hospital, we created a Medical Imaging Clinical Trials Unit (MICTU) in 2016 (Fig. 1) to adequate the participation of the department in trials and to generate resources to foster internal continuous education and research. The unit hired a multidisciplinary team of 8 people with different profiles (1 Nurse, 1 Nursing Assistant, 4 Technicians, 1 Biomedical Engineer, and 1 Business Administration with total costs of 259 K €).

Our objective is to describe how the MICTU was set-up, the resources it uses and main achievements since its creation in 2016.

## 2. Materials and methods

The tasks and organisational needs of the unit, the workflow, the staffing requests, and the indicators of success and performance of the

*Abbreviations:* CRO, Contract Research Organization; CT, Computer Tomography; MICTU, Medical Imaging Clinical Trial Unit; MR, Magnetic Resonance; PI, Principal Investigator; PACS, Picture Archiving and Communication System; PET, Positron Emission Tomography; RECIST, Response Evaluation Criteria in Solid Tumours.

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unit are described in the following sections.

The main MICTU activities related to clinical trials were identified as:

- To store and share all the documentation necessary to perform the clinical trials.
- To handle all the imaging requests and to efficiently schedule image acquisition within the deadlines established by the protocol.
- To ensure and verify that the studies are performed with the adequate quality, and that the results are sent to the centralised imaging laboratory (CoreLab) within the required timeframe.
- To verify that the radiological reports comply with the specific criteria established in the clinical trials.
- To check that any corrections are adequately resolved within the established deadlines.

The main tasks to be performed were identified, as well as the 3 main steps (start-up, execution, and closure) and the department participation (Fig. 2).

### 2.1. *Start-up phase. Documentation required before the clinical trial initiation*

The needed resources and level of collaboration with the Principal Investigators (PIs) and the clinical trial promotor are established with the involvement of the MICTU clinical trial coordinator and nurse, together with department director. The information and documentation related to the study is compiled before the trial starts. The following documents are deemed relevant:

- Site survey: information on the personnel involved in the trial, the role they play and the characteristics of the imaging equipment to be used. The acceptance of this document will be the proof of assurance that our site is eligible to perform the trial.
- Imaging protocol: guidelines for the correct performance of the imaging studies, including the main characteristics and technical specifications.
- Financial report: agreement between the promoter, the PI, and the hospital, stipulating the cost per patient and the indication of whether the studies are performed as ordinary studies, that means that the patient is involved following clinical routine, or paid as extraordinary exams, as stipulated in the financial report.
- Collaboration percentage: the financial agreement is set out according to the unit workload and involvement. We waived the cost if performed with normal procedures and standard clinical practice; 5% if performed with normal procedures but specific tasks (personalised appointment, anonymization and upload service); 10% if performed in addition with specific image acquisition procedures; and 15% if specific and more complex imaging protocols, measurement of the lesions, and specific reports are needed.
- Physicians in charge within the department: responsible for reporting the studies.
- Financial Disclosure Form: to declare any conflicts of interest regarding the participation in the trial.
- Curriculum Vitae: reflecting the main merits, positions, experience and research activities of the professionals participating in the trial.

The clinical trial coordinator at MICTU will verify and evaluate if the unit can comply with the proposal based on available resources. All this documentation is finally validated by the Medical Imaging Department Director before the clinical trials can be carried out.

### 2.2. *Start-up phase. Central laboratory approval*

The involved Contract Research Organization (CRO) or the CoreLab must assess and validate the clinical imaging equipment to be used, the ability to identify and relabel acquired medical images, and the quality of the images acquired (dummy or phantom run). The following issues are considered:

- Training: explanation of required imaging procedures to the technical staff in charge of carrying out the clinical trial.

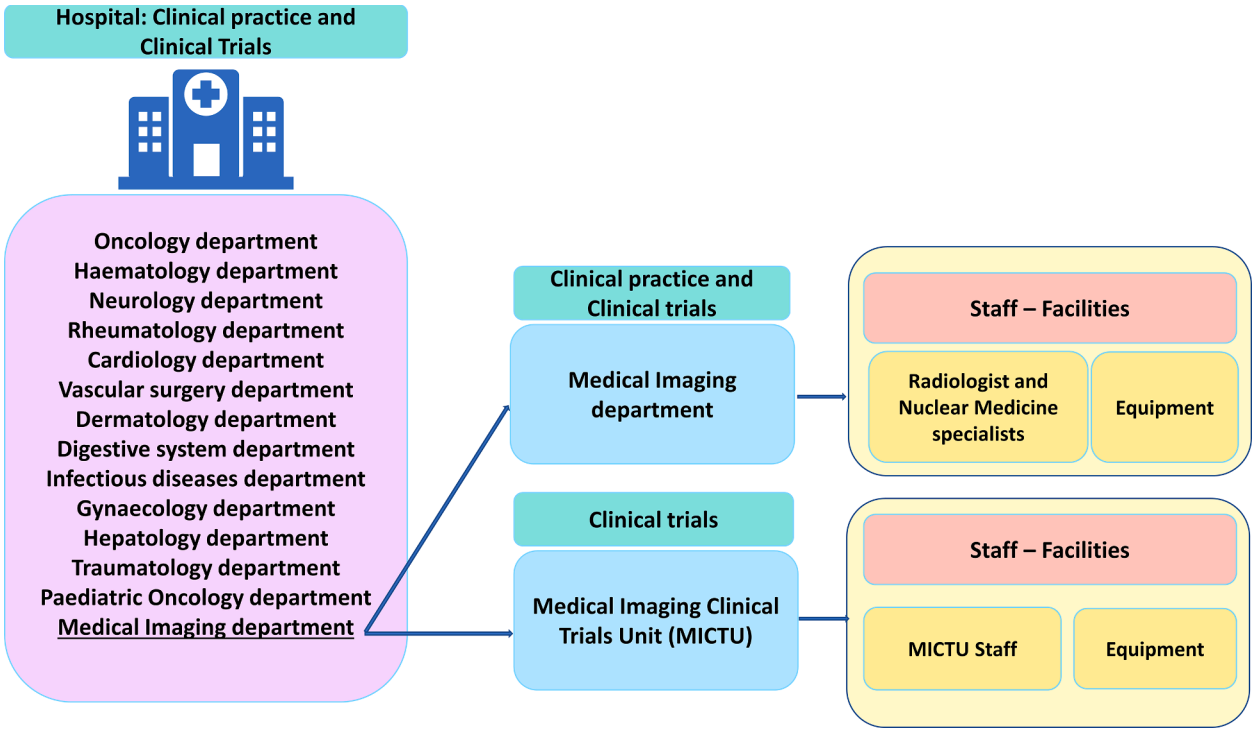


**Fig. 1.** Structure and relationships of the Medical Imaging Clinical Trials Unit.

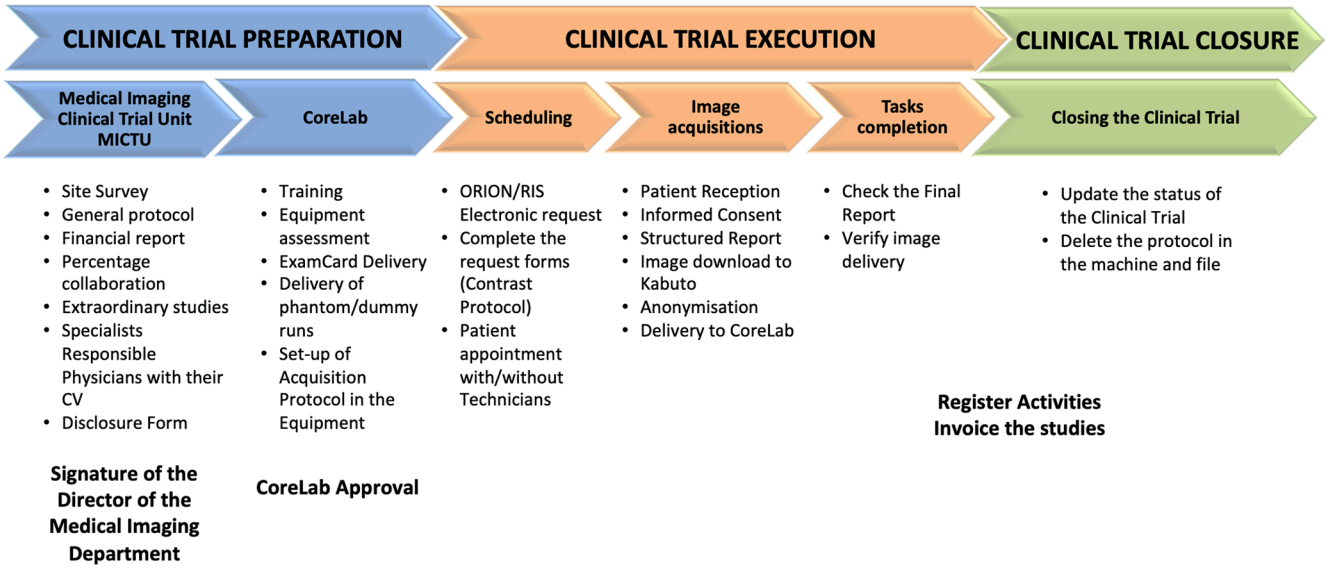


**Fig. 2.** Workflow of a clinical trial in our environment with the main milestones.

- Equipment assessment: evaluation of the specific equipment to be used in the clinical trial. The selection of the equipment is based on the established imaging protocol at the clinical trial (Table 1)
- Acquisition protocol set-up: assessment of the acquisition protocol in the assigned equipment, by sending the Protocol File (Examcard) to the promoter or CoreLab, and validation of the image quality through the acquisition of phantom or dummy run exams.

The centre must be approved prior to start recruitment of the first patients. The MICTU involved staff includes the coordinator of clinical trials and technicians.

### 2.3. Scheduling

All the trial imaging exams are managed by MICTU to ensure a timely and appropriate performance [4]. The Auxiliary nurse is the person in charge of scheduling. In this phase, the following issues are performed:

- Receipt of the electronic imaging request.
- Completion of the relevant information regarding acquisition, report, and submission procedure, ensuring the accessibility to the MICTU staff.
- Patient scheduling, guaranteeing that the appropriate equipment and established timeframes are selected. Studies performed at the hospital-owned equipment are carried out in coordination with the department, while images acquired on research equipment are scheduled by the MICTU technicians. If feasible, patients will be scheduled in the research equipment (at our centre, a 3 T MR and MR/PET units).

**Table 1**
Equipment to performed Clinical Trials in the Medical Imaging Department and the Medical Imaging Clinical Trials Unit.

| Clinical Routine and Clinical Trials (MID) | Only research purpose (MICTU) |
|---|---|
| 6 CT: 2 256-slice CT, 4 64-slice CT | 1 3TMR |
| 3 SPECT/CT with flat detector | 1 PET/MR |
| 2 Dual energy densitometry | |
| 2 digital mammography | |
| 26 Ultrasound system | |
| 14 Digital Radiography suite | |

### 2.4. Image acquisition and report

The unit ensures that the images are acquired according to the defined protocols [5] and that the physician from the department reports with the appropriate response assessment criteria. In this step, the associated personnel are the MICTU technicians. The following aspects are relevant:

- Physical presence of MICTU technical staff to ensure proper positioning of the patient using, when necessary, templates for specific projections.
- Structured reporting in accordance with the trial guidelines to evaluate response. The radiologist and nuclear medicine specialist are in charge of this task.
- The downloading, de-identifying and transferring of acquired images to the CoreLab platform to be evaluated by an Independent Review Committee [6] or to obtain specific quantitative metrics [7].

### 2.5. Completion of the tasks

This checkpoint verifies that all the imaging steps have been performed as agreed. The person in charge of this task is a MICTU technician. Specifically, the unit will:

- Check that stored images stored in the PACS and that the reports were generated and stored in the hospital's information systems prior to the patient's medical visit to the PI.
- Check that the images were sent to the CoreLab.
- Check the inclusion of the study in the MICTU register (Excel file).

### 2.6. Closing the clinical trial

When the trial ends, all the imaging information allows the validation of the activities carried out by MICTU. One technician, one biomedical engineer and the business administrator are involved. The following activities must be ratified:

- Update the status of the clinical trial in the control system, being labelled as "closed."
- Eliminate the specific acquisition protocols from the equipment, storing this information in the acquisition protocol repository.
- Collect the overall generated activity in a spreadsheet.

- Audit the performed studies by sending the recorded activity for verification by the promotor.
- Check that all imaging studies are invoiced in accordance with the economic guidelines, followed our financial workflow (Fig. 3), and can be tracked by the Research Institution's Invoicing Department.

### 2.7. Workflow control

The web-based Redmine software was customised to carry-out the described tasks in an efficient and structured manner [8]. This project management tool allows to centralise all the documentation, scheduling and request of the studies in a single dataset. Redmine was organised to be easily accessible to all the trials staff, allowing the tracking of requests. The tool is particularly useful to provide activity reports, statistics, and to resolve queries by tracking requests [9,10].

The main activities related to this tool are:

- To assign different user profiles: appointment requests and access to procedures of IP address, with full access of the MICTU staff to all study data.
- To review most relevant information of the trial: such as sponsors, EUDRACT, staff assigned to the clinical trials, contrast agents or radiotracers employed, acquisition protocols, and image submission platform.
- To check the status of the trial appointments.
- To verify the uploading of the images to the corresponding platform.
- To supervise that no queries are required due to lack of information at any stage of the study. If so, the software provides its status and the time to be resolved it.
- To compile a report of the activity carried out at each phase.

### 2.8. Staffing needs

Multidisciplinary profiles contribute to the defined tasks, including Nursing, Technicians, Business Administration and Management, and Biomedical Engineering.

The Unit's Nurses are responsible for carrying out the preparation and documentation phase of the trial, guaranteeing the correct collection and availability of the documentation, administration of intravenous contrasts, and patient care. The tasks assigned to the Technicians are related to the appointment of the patients in the required time window, and image acquisition following specified protocols. The Business Administration and Management staff monitor the operation and needs of the Unit, controlling the needed resources, overseeing the carried activities, and invoicing. The Biomedical Engineer is responsible for adapting technical resources, resolving technical incidents, and adjusting the most complex acquisition protocols when necessary.

### 2.9. Key indicators of success

A battery of indicators was selected to provide accurate and relevant information, to assist in decision-making construction. The indicators were agreed on by the MICTU team and generated for each clinical trial phases.

Clinical trial preparation phase:

- Average time to open a clinical trial: mean time taken by the Unit to carry out the necessary procedures so that patients could be included in the trial. Defined as the number of days elapsed between the clinical trial notification and setting up all the requirements to carry out the studies.
- Number of annually opened clinical trials: number of trials in which the MICTU collaborates per year.
- Generated queries and response time: information from the queries register created in Redmine.

Clinical trial execution phase:

- Total number of imaging studies per year: total number of MICTU studies from Redmine registry.
- Number of acquisitions per modality per year: extracted from Redmine.
- Average appointment allocation time: time elapsed between the PI requests and patients scheduling.

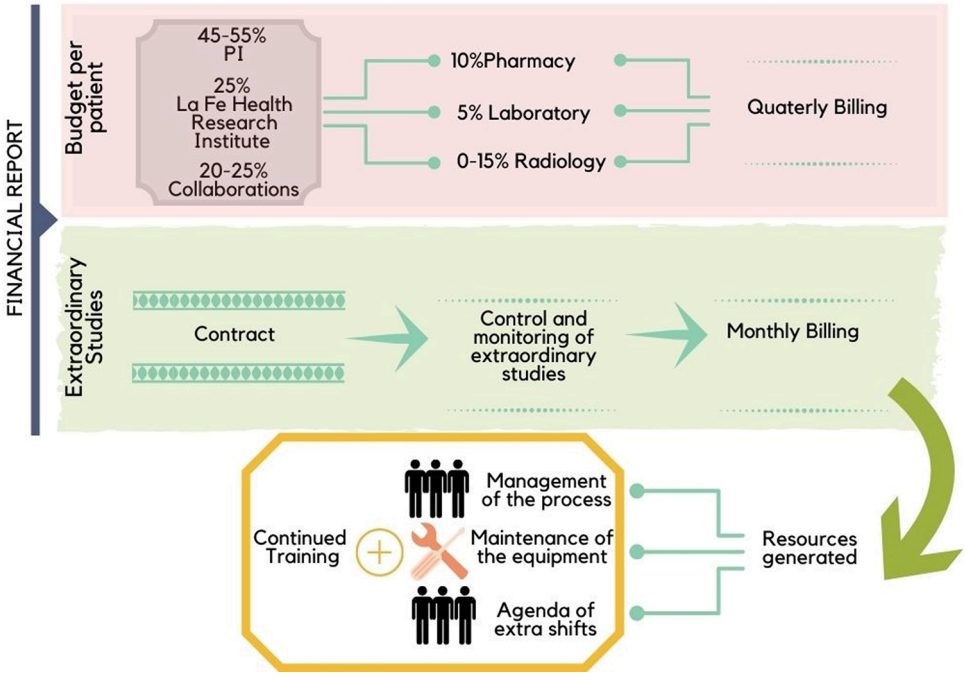


**Fig. 3.** MICTU financial management workflow.

- Generated queries and response time, mainly due to errors in scheduling, modality and protocol.

Finalization of the clinical trial

- Number of extraordinary acquisitions generated per year: these exams do not fall within normal clinical practice, including complex sequences, specific acquisition protocols or singular reporting.
- Annual generated amount: includes a breakdown between the amount generated with the equipment owned by the hospital and the equipment owned by our research institute.
- Satisfaction survey launched to the different requesting departments: to detect areas for improvement in the unit and to solve possible deficiencies detected in advance. An example of a satisfaction survey is included in Annex 2.

## 3. Results

Before the establishment of the MICTU there was no information regarding the number of clinical trials with involvement of the Medical Imaging Department, the extraordinary studies were not register, most studies were performed as clinical routine, and there was no traceability of the imaging activity within the trials. The MICTU indicators related to the carried-out image acquisitions reflect the evolution of MICTU activity, enabling decisions to be taken when allocating resources.

1) Clinical trial preparation:

In the preparation phase, the average time to approve a clinical trial in our unit was 15 ± 12 days (range 1–54 days) from the request for collaboration until the formal e agreement. However, the total average time until the initiation of the trial was 82 ± 61 days (range, 3–214 days). The number of clinical trials worked per year by our unit increased from 80 in 2016 to more than 140 in 2020 (Fig. 4). Regarding the queries received in this start-up phase, the average resolution time was 4–5 days. They were mainly related to:

- Lack of the necessary documentation to open the clinical trial (30%) mainly because the Medical Imaging Department was not included as a collaborative department.
- Inaccuracies in the acquisition protocol, lack of specific protocol or contrasts agent information (20%).
- Errors in phantom runs or dummy runs image acquisition (20%).
- Failure to sign the documents required to start the trial (10%).
- Late reception of training certificates (10%).
- Wrong acquisition protocols due to protocol modifications (10%).

2) Clinical trial execution:

In the execution phase, the MICTU activities decreased a 12% due to the COVID-19 pandemic (145 studies less in 2020 relative to 2019) (Fig. 5). As per the total number of acquisitions in each modality, CT was the main modality up to 2019, although in 2020 there was a PET/CT initiative (Fig. 6). MR represented 22% of exams in the last years. The average allocation time was different by imaging modality, with an average of 3 days from the time a request was received by our Unit.

In this execution phase, 30% of queries did refer to the appointment, mainly due to errors in the request: timing of acquisition, patients who underwent exams outside the trial following usual clinical practice, or because the appointment could not be made within the established timeframe due to an excessive workload. Errors in performing the right imaging protocol (40% of queries in this phase) were due to deviations from the acquisition protocol, patient movement, delivery of the contrast agents, and discrepancies between the Data Transmittal Form and the image. Errors in de-identifying the study and in the transmission of images account for 15% of the queries, mostly due to errors in the platform, incomplete de-identification of the patient's data, and mistakes in the internal identifiers (IDs) in the trial. The average response time in this phase was 3 days.

3) 4Finalization of the clinical trial:

Relevant indicators in the trial closure included extraordinary acquisitions (complex sequences, specific protocols and singular reporting) based on the economic reports provided by the trial promoter (Fig. 7). The main clinical trials handled by our unit and surveyed here were related to Oncology (50.7%), Haematology (11.2%), Neurology (10.9%), Paediatric Oncology (7.6%), Dermatology (3.8%) and Digestive (3.8%) departments. Trials related to the Radiology Department represent (0.8%) were scarce (Fig. 8).

In reference to the resources used in the closing phase, a ratio was made between the resources generated by the Unit and the MICTU overall annual budget (Fig. 9). MICTU experienced a constant growth since 2016 and its weight with respect to the budget managed by MICTU stands at 1.33% (the percentage that MICTU represents in relation to the budget managed by our department). Only 6% of the trials were not funded. The obtained Unit resources are dedicated to the ongoing training of the involved healthcare professionals and to guarantee the sustainability of the Unit's resources (Table 2). Note that in 2020, due to COVID, the percentage dedicated to training and meeting was drastically reduced. The distribution of the analysis based on funding and type of applicant is represented in Fig. 10.

The trial quality control process impacts on the patients' quality of care [11]. The quality of the trials was measured through the satisfaction surveys carried out in different related departments at the Hospital. The addressed issues were:

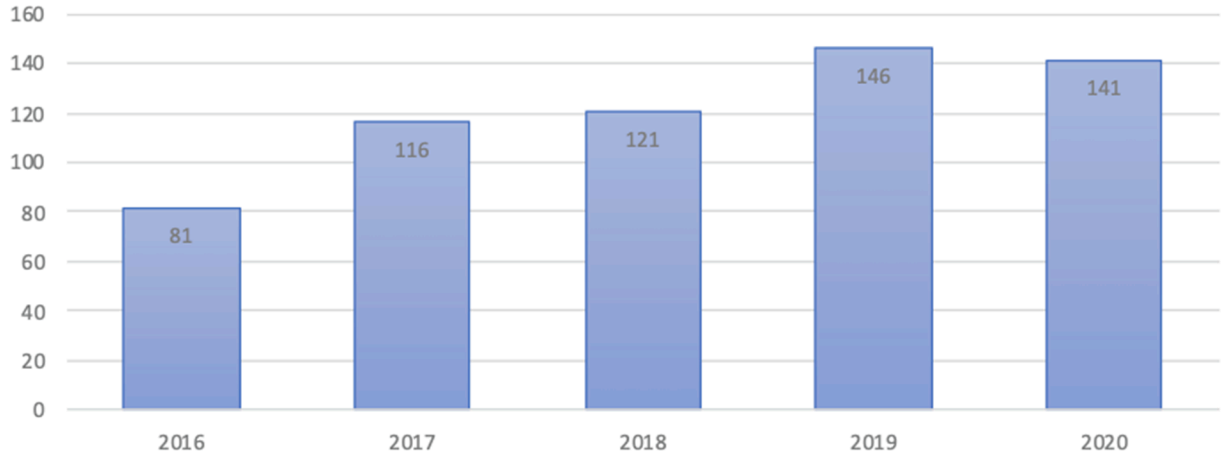


**Fig. 4.** Number of image-based clinical trials that were carried out during 2016–2020.

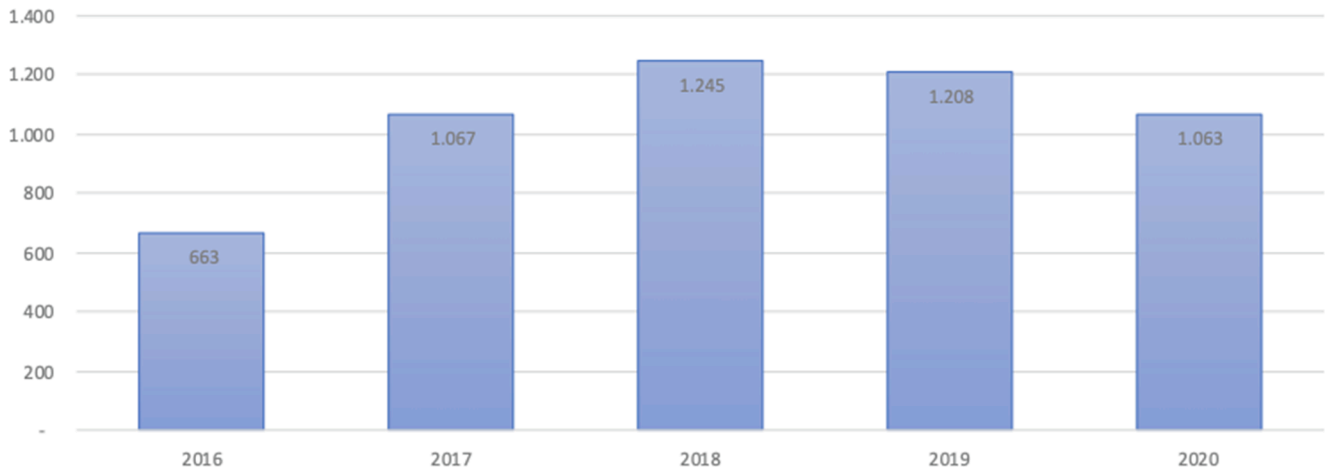


**Fig. 5.** Number of imaging studies handled during 2016–2020.

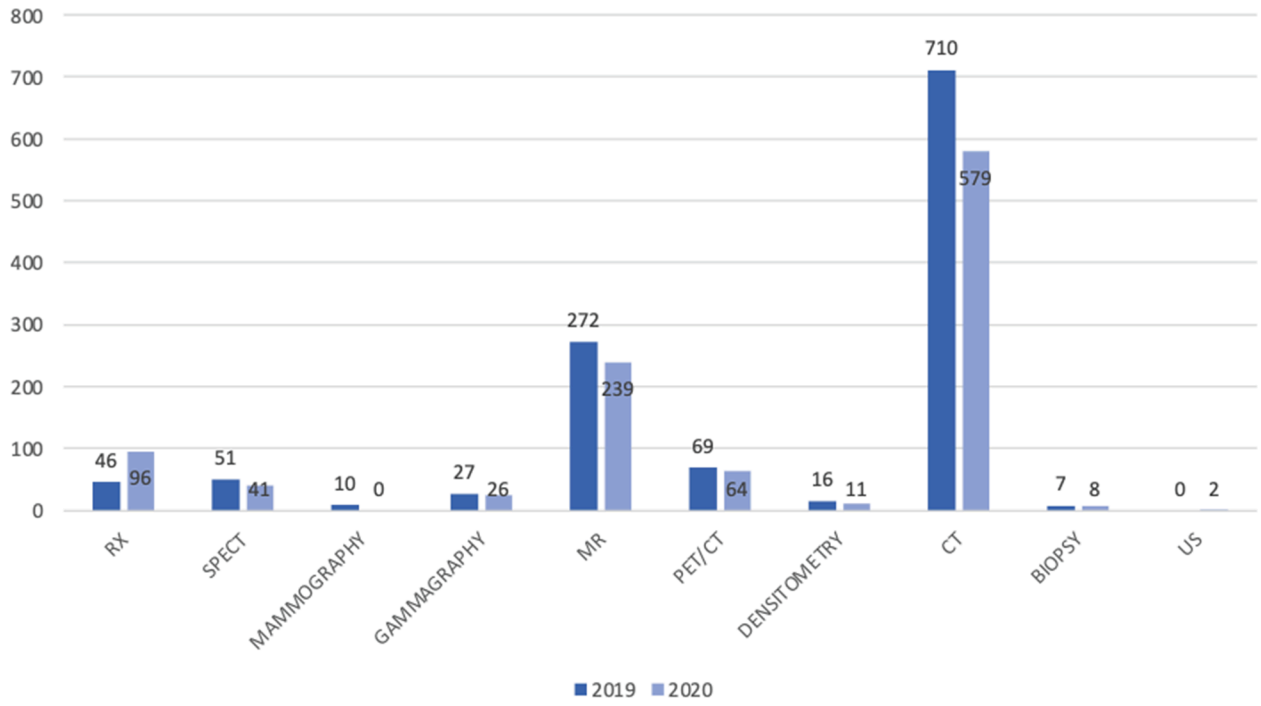


**Fig. 6.** Activity by modality registered in 2019 and 2020.

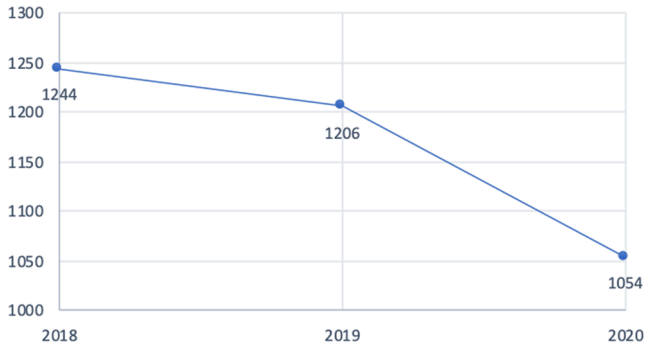


**Fig. 7.** Extraordinary studies handled by the unit from 2018 to 2020.

- Communication and collaboration between the MICTU and the PI's department.
- Ease of use of the Redmine tool to request and monitor appointments.
- Response times and agility in dealing with study requests.
- Delivery of study results on time and in accordance with the criteria established in the clinical trial.
- Aspects for improvement within the MICTU

The Unit have 58 main professional users requesting imaging studies and distributed in 18 departments. The survey was responded by 21 physicians (36.2% respond rate). In terms of the accessibility of the Unit, it was easy to contact (62%) or fully accessible (38%) when required. Aspects such as the willingness of the MICTU to support the resolution of possible incidents showed a majority (86%) of responses with only 14% of non-collaborative responses as it were not always possible to solve problems. More than half of respondents (67%) considered the Redmine tool to be useful or very useful in terms of the requests and the follow-up

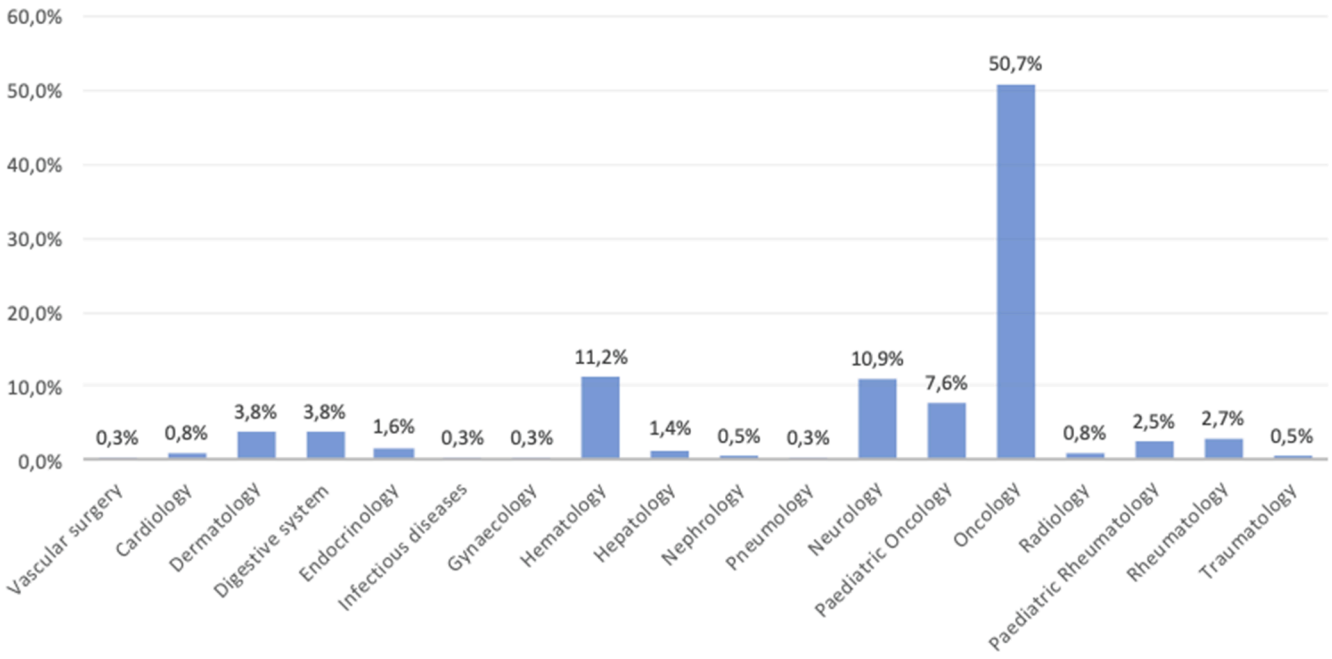


**Fig. 8.** Main departments requesting studies, shown as the percentage of clinical trials by departments in 2020.

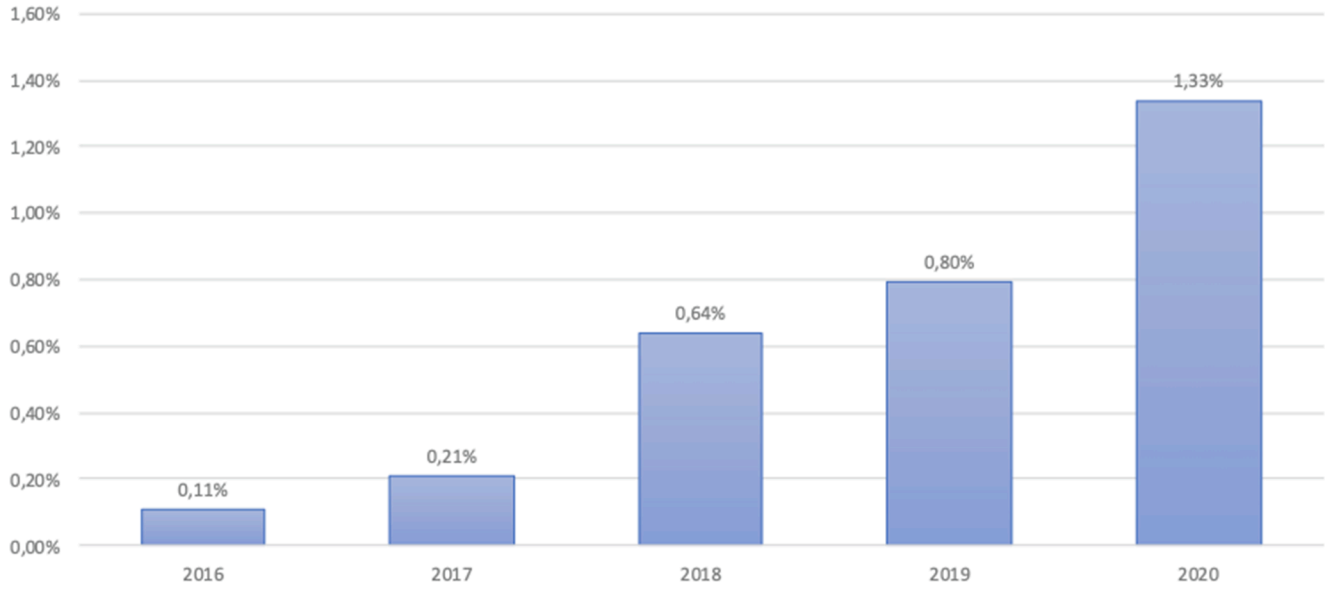


**Fig. 9.** The income generated by the MICTU relative to the budget assigned to the Medical Imaging Department.

**Table 2**
Annual distribution of the expenses dedicated to Human Resources.

| | 2016 | 2017 | 2018 | 2019 | 2020 |
|---|---|---|---|---|---|
| Expenses in ongoing training and meetings | 45% | 29% | 38% | 33% | 9% |
| Expenses in salaries | 55% | 71% | 62% | 67% | 91% |

of patient appointments, indicating it was an easy tool to use. Regarding the appointment response times, 57% of respondents rated the appointment time was adequate or very adequate, with 52% of respondents recognizing that the imaging modality influences the delay in appointment allocation. The imaging modalities with more delay in allocation were PET-TAU, PET-Amyloid, SPECT-FEVI and CT exams. The response time of the MICTU following PI consultation was rated as good or very good (62%). Most responders (90%) agree that the MICTU always offered information regarding delays.

Nearly 62% of the responders stated that the acquisitions were carried out without incident and following the established protocols, while 38% stated that at some point there had been incident related to the acquisitions they coordinated and/or managed. When evaluating the de-identification and image sending times, the Unit had an adequate (76%) level of satisfaction. Finally, the survey highlighted some specific issues to provide a better service:

- Priority should be given to scheduling for screening tests and for reporting.
- Response evaluation criteria might generate problems if the target lesions were not correctly labelled.

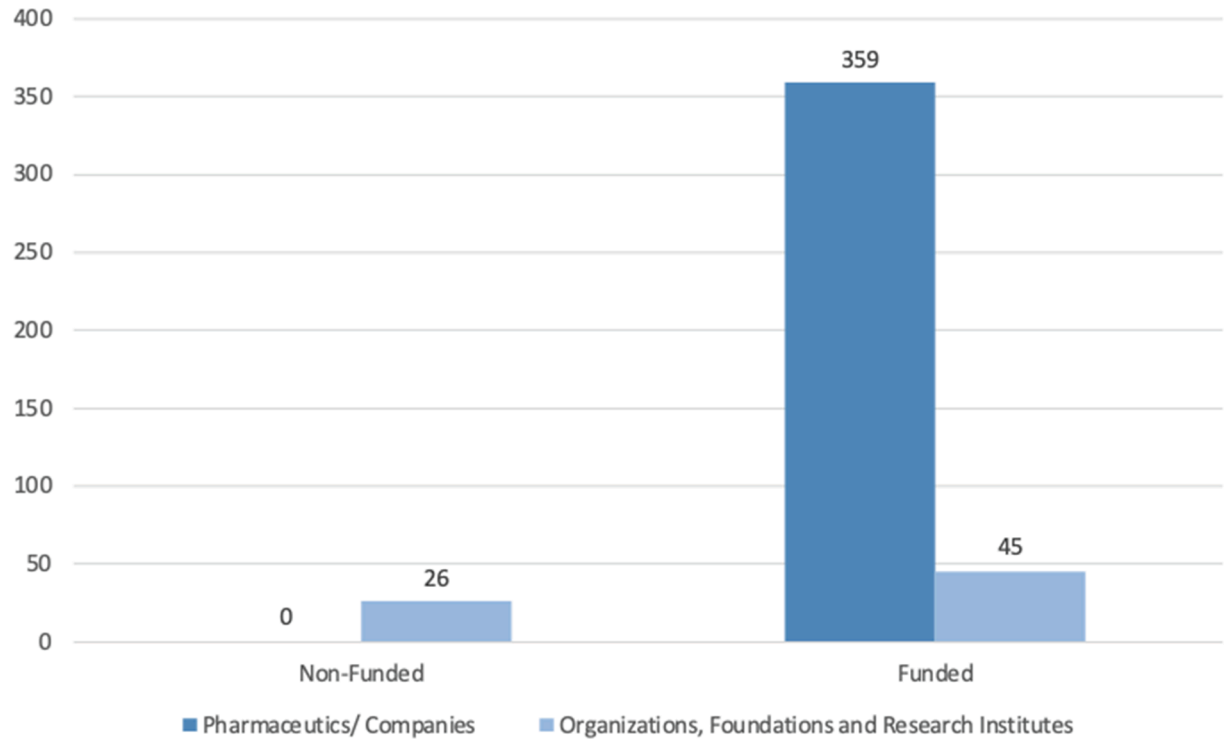


**Fig. 10.** Distribution of Clinical Trials based on funding and applicant.

- Periodic meetings were proposed to co-ordinate trials and the procedures involving different parties.
- Improve the accessibility to sedation process.

The main improvements were defined as:

- The workflow has been significantly simplified thanks to improvements in design and adaptation to the management tools.
- The errors made in the Unit have significantly decreased.
- The staff in charge of the clinical trials have become more specialised in well-defined tasks.
- The use of Redmine has enhanced the control and tracking of the trial activities.
- The design and implementation of the different indicators provides an accurate global vision of the phases, aiding decision-making.
- The implementation of a quality control system based on surveys led to better communication between radiologists and clinicians.

## 4. Discussion

Targeted Clinical Trial units have been set-up at many centres. The IDIVAL Health Research Institute in Spain is a centre that do not have specific imaging equipment dedicated to clinical trials, consisting of 8 staff members who collaborate with the hospital [12]. At IDIPAZ, the Research Institute of another Spanish university centre, there is no clinical trials unit that focuses on imaging, but provide support to researchers in designing, setting-up, management, analysis, and preparation of financial reports [13]. In another situation, VHIO incorporates experts from the Medical Oncology Department, including radiologists, to conduct clinical trials at a university hospital [14], although no specific imaging unit exists. These organizations represent the most frequent case, being composed by trials managers who specialize in and monitor clinical trials, supporting the research groups belonging to the institution.

At the European level, the Centre for Medical Imaging (CMI) from the University College London Hospitals [15] comprises nearly 30 research staff, compounding clinical radiologists, non-clinical basic scientists, and support staff (research nurse, radiographers, and administration). This centre stands out as an exclusive medical imaging centre and has high-performance imaging equipment for use in clinical trials.

The National Cancer Imaging Translational Accelerator (NCITA) is a UK network of clinical research imaging infrastructures supported by a Cancer Research UK Accelerator Award. One of its cross-institutional units is related with the Imaging Clinical Trials Unit, which supports and coordinates studies where imaging is required. In addition, this Unit works closely with the Quality/Control Unit and the Repository Unit [16].

The Clinical Trials Unit (CTU) is a central facility of the University of Freiburg's Faculty of Medicine and Medical Centre. The unit is integrated into the clinical departments at the University Medical Centre. The Project Management Clinical Trials consist of a Project Management area, Project Assistance, Clinical Monitoring and Study Nurse Services [17].

Some of these units, including our, are members of the European Clinical Research Infrastructures Network (ECRIN), a public non-profit organisation that connects scientific partners and networks across Europe to facilitate multinational clinical research. ECRIN represents a link between clinical trial sponsors and researchers, providing advisory and management services to overcome the bureaucratic hurdles of multinational trials.

For any targeted imaging clinical trial unit to function properly, it is essential to establish a collaborative environment with the hospital's management and clinical departments involved in the trials. This unit must be equipped with the necessary human resources and management tools. In our experience, a project management software is pivotal in controlling and monitoring the clinical trial activity, as well as allowing efficient communication with clinicians and trial managers. Our Redmine solution also enables financial control of resources to be distributed in a transparent environment. It is essential to reinvest the obtained resources in educational and training activities for the involved professionals. In our experience, the satisfaction perceived in the involved departments, and the visibility and capabilities of our Medical Imaging

Department, notably improved thanks to the involvement and specialisation of the MICTU staff.

It is recognized that imaging has an important and growing role in the evaluation of new treatments in clinical trials [18]. According, the use of imaging to assess the response to new drugs and devices is increasing, evaluating the induced changes through several response criteria [19,20,21,22]. Radiomics might also help in this assessment by evaluating the tissue changes by highlighting the relevant phenomena that can be extracted from images through which predictive models can be constructed based on anatomopathological correlations [23]. The increased activity on clinical trials fosters the creation of targeted imaging clinical trial units [24].

## 5. Conclusion

The creation of a Medical Imaging Clinical Trials Unit focused on the integral management of images represents added value in the clinical trial execution chain. These units should be member of national and international collaborative networks, offering new opportunities to reinforce the role of imaging in trials by establish new relationships.

## CRediT authorship contribution statement

**Ana Penadés-Blasco:** Conceptualization, Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing. **Sonia Ginés-Cárdenas:** Data curation, Writing – review & editing. **Amadeo Ten-Esteve:** Data curation, Software, Writing – review & editing. **Pilar Bello Arques:** Writing – review & editing. **Juan M. Soriano Llobera:** Writing – review & editing. **David Vivas Consuelo:** Writing – review & editing. **Luis Martí-Bonmatí:** Conceptualization, Formal analysis, Investigation, Methodology, Supervision, Validation, Writing – original draft, Writing – review & editing.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejrad.2021.110099.

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